

Comments

The Uncertain Application of the Right of Privacy in Personal Medical Decisions: The Laetrile Cases

But when intemperance and cases of illness increase in a state, are not both courts of justice and houses of medicine often being opened, and are not the arts of both lawyer and doctor held in high import . . . ?—Plato¹

In the fifteen years since the right of privacy was given its modern enunciation² by the United States Supreme Court, its scope has been defined to include such medically related decisions as procreation,³ abortion of a fetus,⁴ and contraception.⁵ The Court, however, has so far declined to decide whether the right of privacy is a fundamental one in the context of an ill person's right to make an informed choice among various medical treatment options. The unsettled application of a medical right to privacy is well illustrated by the conflicting decisions of state and federal courts faced with cancer patients' demands for the federally proscribed drug Laetrile. This Comment will briefly survey the history of Laetrile and the Laetrile cases that have addressed the right of privacy argument, and will then discuss the right of privacy doctrine in the constitutional context of the federal government's approach to cancer.

I. BACKGROUND

A. *The Right of Privacy*

The specific constitutional right to privacy was born in the 1965 case of *Griswold v. Connecticut*,⁶ in which the Court found the right to be fundamental though not set out in the Constitution.⁷ Justice Douglas' opinion found various guarantees in the Bill of Rights within whose "penumbras" were created zones of privacy.⁸ Among these guarantees were the right of association in the penumbra of the first amendment, the third amendment's prohibition against peacetime quartering of soldiers, the fourth amendment's prohibition of unreasonable searches and seizures, the fifth amendment's self-

1. THE REPUBLIC OF PLATO 405 (J. Adam ed. 1938) (K. Christensen translation, after Jowett).

2. *Griswold v. Connecticut*, 381 U.S. 479 (1965).

3. *Eisenstadt v. Baird*, 405 U.S. 438 (1972).

4. *Roe v. Wade*, 410 U.S. 113 (1973).

5. *Carey v. Population Services Int'l*, 431 U.S. 678 (1977).

6. 381 U.S. 479 (1965).

7. *Id.* at 482, 485.

8. *Id.* at 484.

incrimination clause, and the ninth amendment's reservation of rights not specifically mentioned anywhere in the Constitution.⁹

In *Griswold*, the right of privacy was held to include a married couple's right to practice contraception.¹⁰ As a fundamental right, it invoked the Court's strict scrutiny¹¹ of the relevant state statutes that forbade the use of contraceptives. *Griswold*'s protection was extended to an unmarried person's right to contraceptives in the 1972 case of *Eisenstadt v. Baird*.¹²

In the 1973 *Abortion Cases*,¹³ the Court found that a woman's decision to abort a fetus was protected by the constitutional right of privacy.¹⁴ The Court held, however, that the right is not absolute and can be countered by a sufficiently compelling state interest.¹⁵ In brief, the Court found that as a fetus matures the state's interest in protecting the health of the mother increases, eventually to the point of overcoming the woman's right of privacy.¹⁶ The 1976 abortion case of *Planned Parenthood v. Danforth*¹⁷ saw another comparison of state interests with the right of privacy. Where the state regulated without prohibiting, the Court was willing to uphold the statute;¹⁸ where it gave someone other than the pregnant woman veto power over the abortion,¹⁹ or effectively denied the most widely practiced and safest of the abortion medical procedures,²⁰ the Court struck down the statute.

Regulation, as distinct from prohibition, was the key to the 1977 *Whalen v. Roe*²¹ decision, where a New York statute required extensive record-keeping of the names of lawful users of certain narcotic drugs. The plaintiffs attempted to invoke the developing right of privacy in opposition to the law,²² but the Court held that the risks of unauthorized disclosure of confidential information—speculative as they were—did not outweigh the state's interest in regulating dangerous drugs.²³ The crucial factor was that no "individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use needed medication."²⁴ In this paragraph, which was to be subject to diametrically opposite interpretations by lower courts and commentators,²⁵ the Court went on to state that "[a]lthough the State no doubt could prohibit entirely the use of particular Schedule II drugs,

9. *Id.* Justice Goldberg's concurring opinion stressed the ninth amendment. *Id.* at 487.

10. *Id.* at 485-86.

11. *Id.* at 485. See text accompanying notes 33-35 *infra*.

12. 405 U.S. 438 (1972).

13. *Roe v. Wade*, 410 U.S. 113 (1973); *Doe v. Bolton*, 410 U.S. 179 (1973).

14. 410 U.S. 113, 153 (1973).

15. *Id.* at 154-55.

16. *Id.* at 156, 162-63.

17. 428 U.S. 52 (1976).

18. *Id.* at 65-67, 79-81.

19. *Id.* at 67-75.

20. *Id.* at 75-79.

21. 429 U.S. 589 (1977).

22. *Id.* at 598, 599.

23. *Id.* at 600, 601.

24. *Id.* at 603.

25. See text accompanying notes 179-83 *infra*.

it has not done so. This case is therefore unlike those in which the Court held that a total prohibition of certain conduct was an impermissible deprivation of liberty."²⁶ The Court included a footnote in this statement which read: "It is, of course, well settled that the State has broad police powers in regulating the administration of drugs by the health professions."²⁷ As will be seen,²⁸ some courts have taken the first sentence out of context so that standing alone it appears to allow the state absolute power to prohibit certain dangerous drugs. The next sentence, however, at least implies that a total prohibition is an impermissible deprivation of liberty.

Since the right of privacy is not explicitly mentioned in the Constitution,²⁹ and since it has been found under the "penumbras" of the first, third, fourth, fifth, ninth, and fourteenth amendments, among others,³⁰ it is not surprising that there is confusion about the extent of the right and the level of review to be invoked once the right is found.³¹ The level of review under the equal protection clause of the fourteenth amendment is fairly standardized in the Court's decisions.³² If the Court finds that the state legislation under review "operates to the disadvantage of some suspect class or impinges on a fundamental right explicitly or implicitly protected by the Constitution,"³³ the Court will apply strict scrutiny of the statute. "If not, the [legislative] scheme must still be examined to determine whether it rationally furthers some legitimate, articulated state purpose and therefore does not constitute an invidious discrimination."³⁴ Since a statute rarely survives strict scrutiny and rarely fails the rational basis test,³⁵ this two-step analysis has been criticized as being actually a single-step approach, with the outcome decided at the threshold.³⁶

Thus, it is not surprising that the Court, in fashioning the evolving right of privacy, has striven to retain some flexibility by treating it as less than absolute.³⁷ Unlike most fundamental rights, the right of privacy has had to give way before the "compelling state interest"³⁸ that seems so hard to find when other fundamental rights have been reviewed. Courts and commentators have

26. 429 U.S. 589, 603 (1977) (footnote omitted).

27. *Id.* at 603 n.30.

28. See text accompanying notes 180-83 *infra*.

29. *Griswold v. Connecticut*, 381 U.S. 479, 482 (1965).

30. *Id.* at 481, 484, 487; *Roe v. Wade*, 410 U.S. 113, 152-53 (1973).

31. See Glancy, *The Invention of the Right to Privacy*, 21 ARIZ. L. REV. 1 (1979).

32. J. NOWAK, R. ROTUNDA & J. YOUNG, HANDBOOK ON CONSTITUTIONAL LAW 416, 523-25 (1978).

33. *Maher v. Roe*, 432 U.S. 464, 470 (1977), quoting *San Antonio Independent Sch. Dist. v. Rodriguez*, 411 U.S. 1, 17 (1973).

34. *Id.* (bracketed material added by the Court in *Maher*).

35. J. NOWAK, R. ROTUNDA & J. YOUNG, HANDBOOK ON CONSTITUTIONAL LAW 524-25 (1978).

36. Gunther, *Foreword: In Search of Evolving Doctrine on a Changing Court: A Model for Newer Equal Protection*, 86 HARV. L. REV. 1 (1972); Nowak, *Realigning the Standards of Review Under the Equal Protection Guarantee—Prohibited, Neutral, and Permissive Classifications*, 62 GEO. L.J. 1071 (1974). See *Massachusetts Bd. of Retirement v. Murgia*, 427 U.S. 307, 318-21 (1976) (Marshall, J., dissenting).

37. *Roe v. Wade*, 410 U.S. 113, 153-54 (1973).

38. See text accompanying notes 16-20 *supra*.

read this apparent middle ground variously. In *People v. Privitera*,³⁹ the California Supreme Court chose to read *Roe v. Wade* as applying a rational basis test to the right of privacy-abortion right, at least when a danger to health exists.⁴⁰ On the other hand, Justice Rehnquist read *Wade* and its companion case *Doe v. Bolton* as requiring close scrutiny,⁴¹ and Justice Stewart's concurring opinion in *Wade* terms the test "'particularly careful scrutiny.'" ⁴² As one author has put it: "The compelling interest test [of *Roe v. Wade*] is not the same 'compelling state interest test' which is employed in suspect classification/equal protection analysis" ⁴³ Another author finds a "rational basis-compelling interest" approach⁴⁴ to privacy in the Court's opinion in *Carey v. Population Services International*,⁴⁵ whereas Justice Powell's concurring opinion in that case interpreted the test used as being the "strictest standard of judicial review."⁴⁶ While it is a truism that the privacy cases decided by the Court are confusing,⁴⁷ the pattern seems to be that the Court has left the rigid bounds of the strict scrutiny or rational basis dichotomy and is now willing to look for compelling state interests as possibly countervailing any fundamental right of privacy it may have found.

B. Right to Die by Refusing Treatment

There is no Supreme Court ruling on whether an individual has a constitutional right to reject life-saving medical treatment.⁴⁸ The leading state case is the well-publicized *In re Quinlan*,⁴⁹ in which the New Jersey Supreme Court held that the developing right of privacy was presumably "broad enough to encompass a patient's decision to decline medical treatment under certain circumstances" ⁵⁰ The court decided *Quinlan* on state constitutional grounds.⁵¹ The "certain circumstances" do not include the right of an accident victim to reject life-saving medical treatment;⁵² rather, a victim of a major, permanently crippling disease has the right to decline life-prolonging treatment.⁵³ The narrowness of the *Quinlan* ruling may result from the com-

39. 23 Cal. 3d 697, 591 P.2d 919, 153 Cal. Rptr. 431, cert. denied, 444 U.S. 949 (1979).

40. *Id.* at 703, 591 P.2d at 922, 153 Cal. Rptr. at 434.

41. *Roe v. Wade*, 410 U.S. 113, 173-74 (1973) (Rehnquist, J., dissenting); *Doe v. Bolton*, 410 U.S. 179, 223 (1973) (Rehnquist, J., dissenting).

42. *Roe v. Wade*, 410 U.S. 113, 170 (1973) (Stewart, J., concurring).

43. Jackson, *The Coerced Use of Ritalin for Behavior Control in Public Schools: Legal Challenges*, 10 CLEARINGHOUSE REV. 181, 189 (1976).

44. Ehrlich, *Freedom of Choice: Personal Autonomy and the Right to Privacy*, 14 IDAHO L. REV. 447, 466 (1978).

45. 431 U.S. 678 (1977).

46. *Id.* at 703 (Powell, J., concurring in part). Arguably, a third, middle level of review—a substantial relationship test—can be posited from the majority opinion. *Id.* at 691.

47. Glancy, *The Invention of the Right to Privacy*, 21 ARIZ. L. REV. 1 (1979).

48. J. NOWAK, R. ROTUNDA & J. YOUNG, HANDBOOK ON CONSTITUTIONAL LAW Supp. at 74 (1978).

49. 70 N.J. 10, 355 A.2d 647, cert. denied, 429 U.S. 922 (1976).

50. *Id.* at 40, 356 A.2d at 663.

51. *Id.*

52. *Id.* at 35, 39, 355 A.2d at 661, 663.

53. Unlike the case of a young woman whose life depended on surgery and blood transfusion but who, being unconscious, was unable to give informed consent, *John F. Kennedy Memorial Hosp. v. Heston*, 58 N.J. 576, 279 A.2d 670 (1971), Karen Quinlan's case was "diametrically opposite [in that she could only] vegetate a

plications of Karen Quinlan's incompetence to represent herself;⁵⁴ to give the relief sought (disconnection from life maintenance systems)⁵⁵ the court first had to give Quinlan's father the right to make the decision in his daughter's name.⁵⁶ In any event, the court summed up its privacy considerations with a balancing test when it wrote that "the State's interest *contra* weakens and the individual's right to privacy grows as the degree of bodily invasion increases and prognosis dims."⁵⁷

More recently, the Florida Supreme Court upheld the right of a competent, adult patient, under the privacy doctrine, to refuse life-prolonging treatment.⁵⁸ A federal district court has found that the right of mental patients to refuse treatment in nonemergency situations "is best founded on the emerging right of privacy,"⁵⁹ although it cautioned, as the United States Supreme Court did in *Roe v. Wade*,⁶⁰ that the right is not absolute.⁶¹ Similarly, the Massachusetts Supreme Judicial Court held that a mental patient, through his guardian, could reject the painful proffered treatment for his cancer.⁶² The decision was based on the right of privacy.⁶³ The court reiterated this reasoning under the privacy doctrine in *Marcoux v. Attorney General*,⁶⁴ where it said that the individual's choice to accept or decline medical treatment is normally beyond veto by the state.⁶⁵

Contrary holdings have almost invariably appeared in emergency situations in which an injured person is seeking to reject, typically for religious reasons, treatment that is clearly life-saving and not inordinately painful, such as a blood transfusion.⁶⁶

C. The Laetrile Climate

The increasing death rates for many kinds of cancer in this century,⁶⁷ together with the fear of the pain associated with many forms of the disease, would inevitably have kept the disease prominent in the public mind.⁶⁸ The

few measurable months with no realistic possibility of returning to any semblance of cognitive or sapient life." 70 N.J. 10, 39, 355 A.2d 647, 663 (1976).

54. Karen Quinlan was comatose, and in a chronic and persistent "vegetative" state. *Id.* at 25, 355 A.2d at 655.

55. 70 N.J. at 18, 355 A.2d at 651.

56. *Id.*

57. *Id.* at 41, 355 A.2d at 664 (emphasis in original).

58. *Satz v. Perlmutter*, 379 So.2d 359 (Fla. 1980), *aff'g* 362 So.2d 160 (Fla. App. 1978).

59. *Rennie v. Klein*, 462 F. Supp. 1131, 1144 (D.N.J. 1978).

60. 410 U.S. 113, 153-54 (1973).

61. *Rennie v. Klein*, 462 F. Supp. 1131, 1145 (D.N.J. 1978).

62. *Superintendent of Belchertown State Sch. v. Saikewicz*, 373 Mass. 728, 370 N.E.2d 417 (1977).

63. *Id.* at 739, 370 N.E.2d at 424.

64. 375 Mass 63, 375 N.E.2d 688 (1978).

65. *Id.* at 66, 375 N.E.2d at 690.

66. *E.g., In re Quinlan*, 70 N.J. 10, 39, 355 A.2d. 647, 633 (1976). *See, e.g.* Application of the President and Directors of Georgetown College, Inc., 331 F.2d 1000, *cert. denied*, 377 U.S. 978 (1964) (emergency victim given life-saving blood transfusions against religiously motivated refusal by victim and her husband); *Raleigh Fitkin-Paul Morgan Memorial Hosp. v. Anderson*, 42 N.J. 421, 201 A.2d 537, *cert. denied*, 377 U.S. 985 (1964) (similar situation involving pregnant woman).

67. R. RIGDON, *TRAUMA AND CANCER* 12-13, 16 (1975).

68. R. RETTIG, *CANCER CRUSADE* 2 (1977).

campaign that accompanied the effort which eventually led to the National Cancer Act of 1971 may have not only inflamed those fears, but encouraged undue hopes for medicine's ability to find a cure.⁶⁹ One author calls the campaigners' language that of "exaggeration [and] hyperbole,"⁷⁰ and implies that they were engaging in a "polite deception"⁷¹ of Congress and the public about the prospects for advances against cancer. Recent claims by the President's Cancer Panel established by the National Cancer Act have been "more modest and subdued":⁷² "We are, in truth, profoundly ignorant about the real nature of cancer. We do not really understand what happens."'⁷³

In spite of the massive amounts of federal money infused into the cancer research program, some scientists claim that there has been no improvement in the five-year survival rate of cancer victims since the 1950s.⁷⁴ Even if one assumes that there have been significant advances against cancer in general (and there are apparently uncontroverted findings of progress against a few specific kinds of cancers⁷⁵), the price has been high to the patients faced with the rigors of surgery, radiation and, most notably, chemotherapy. As one patient put it, chemotherapy is "a fate worse than death."⁷⁶ Cancer researchers themselves acknowledge the severe side effects of chemotherapy that induce patients to drop out of the treatment programs and deter still others from starting chemotherapy.⁷⁷

Quack cancer "cures" have been foisted on a willing public for decades.⁷⁸ Government-approved treatments are still disappointing in their efficacy⁷⁹ and painful in their side effects.⁸⁰ Approved treatments are all the more frustrating and disappointing for cancer victims today who have been expecting dramatic breakthrough from the cancer "crusade" kicked off by

69. *Id.* at 317-18.

70. *Id.* at 318.

71. *Id.* at 320.

72. *Id.* at 319.

73. *Id.*, quoting PRESIDENT'S CANCER PANEL: 1977 REPORT.

74. *Id.* at 321. The Five-Year Survival Rate measures the number of patients who are still living five years after the date of diagnosis. It does not measure the cure rate. Even taking the 1975 survey of survival rates at face value, see Cutler, Myers & Green, *Trends in Survival Rates of Patients with Cancer*, 293 NEW ENGLAND J. MED. 122 (1975), the claim is less than a ten percent improvement in 97 percent of cancers since 1950. Critics have pointed out that even this modest claim can be accounted for purely via earlier diagnosis; for example, diagnosing a cancer six months earlier than usual will automatically effect a ten percent improvement in the Five-Year Survival Rate. See Garvin, *Survival Rates Calculated from Date of Diagnosis*, 293 NEW ENGLAND J. MED. 1045 (1975).

75. R. RETTIG, *CANCER CRUSADE* 5, 7-8 (1977).

76. U.S., April 3, 1979, at 19. A Maryland jury has awarded \$800,000 to a woman for her pain and suffering in undergoing chemotherapy as a result of a mistaken diagnosis of cancer. The plaintiff is trying to decide whether to accept the judge's remittitur of \$400,000 or a new trial. Washington Post, Feb. 8, 1980, § B, at 1, col. 1.

77. "[T]he treatment of cancer with certain drugs induces severe side effects in many people [who] either discontinue or limit the amount of drug that we give them because of the . . . side effects." Letter from N. Larrimer, M.D., to State Senator Stano (July 26, 1979).

78. 42 Fed. Reg. 39,768, 39,795-96 (1977).

79. See text accompanying notes 73-74 *supra*.

80. See text accompanying notes 76-77 *supra*. "A real need to obtain relief from the upsetting cancer chemotherapy treatment exists." Cohen, *Marijuana: Does It Have a Possible Therapeutic Use?*, 240 J.A.M.A. 1761, 1763 (1978).

the National Cancer Act of 1971.⁸¹ This adds up to fertile ground for any proposed cure with a glimmer of hope, especially one that inflicts less suffering than the approved chemotherapies. Of all the unsanctioned remedies proffered in the last two decades, none has had the staying power of Laetrile, the drug that refuses to disappear despite the efforts of federal drug regulators and a majority of the medical community.⁸²

Laetrile has been around since the 1950s.⁸³ With varying degrees of accuracy, it is also called amygdalin and, in an unsuccessful effort to avoid being classed as a drug, vitamin B-17.⁸⁴ Some of its proponents have claimed that it works by releasing cyanide in the body in such a way as to attack cancerous cells more than normal cells.⁸⁵ Other proponents claim that it works in some unknown way against cancer cells.⁸⁶ Still others assert that it is a nutritional supplement which, rather than attacking the cancer itself, promotes the well-being of the body's immune system, thus helping it fight the cancerous growth naturally.⁸⁷

In addition to those who claim that Laetrile is an active agent in resisting cancer, there are those who merely allege that the substance eases the pain of cancer and its approved treatments;⁸⁸ they tout Laetrile as a supplement rather than an alternative to conventional treatment. Almost all Laetrile supporters insist that its ingestion be part of a larger nutritional program aimed in part at combating the wasting effects of cancer.⁸⁹

Medical opinion has been generally hostile to Laetrile.⁹⁰ Federal drug laws require extensive clinical testing, first on animal models, then on human volunteers, before a cancer drug can be licensed for even limited distribution.⁹¹ The responsible agency, the Federal Food and Drug Administration (FDA), can issue temporary licenses for experimental testing.⁹² Without the experimental license, the necessary documentation cannot be assembled in

81. See text accompanying note 69 *supra*.

82. "However much we may wish it to, Laetrile is not about to disappear." Relman, *Laetrilomania—Again*, 298 NEW ENGLAND J. MED. 215 (1978).

83. 42 Fed. Reg. 39,768, 39,771-72 (1977).

84. *Id.* at 39,770, 39,801.

85. *Id.* at 39,773-74.

86. *Id.* at 39,772-73.

87. *Id.*

88. *Id.*

89. *Id.* at 39,785-86. The wasting effect—cachexia—is a leading cause of death among cancer victims. Laetrile supporters claim that the drug increases appetite and reverses the cachexia. *People v. Privitera*, 23 Cal. 3d 697, 715, 591 P.2d 919, 929, 153 Cal. Rptr. 431, 441 (Bird, C. J., dissenting), *cert. denied*, 444 U.S. 949 (1979).

90. 42 Fed. Reg. 39,768, 39,781 (1977); Ingelfinger, *Laetrilomania*, 296 NEW ENGLAND J. MED. 1167 (1977).

91. 21 U.S.C. § 355 (1976), prohibits the distribution of any "new drug" unless the federal government has approved an application supported by substantial evidence of the drug's safety and effectiveness. The authority for approval is delegated from the Secretary of Health, Education, and Welfare to the Commissioner of the Food and Drug Administration. 21 C.F.R. § 5.1(a) (1) (1980). The Commissioner may grant investigational licenses provided that adequate preclinical tests, including tests on animals, have taken place. 21 U.S.C. § 355(i) (1) (1976).

92. 21 U.S.C. § 355(i) (1976).

the required fashion, and the FDA's refusal to issue the license has prevented definitive answers to the question of Laetrile's efficacy or safety.⁹³

A drug must be safe as well as efficacious under current federal drug law before it can be approved for distribution.⁹⁴ FDA refusal to give Laetrile a chance to prove or disprove itself has not sat well with a number of trial judges faced with demands from cancer patients who wish to use the forbidden drug.⁹⁵ From the standpoint of scientifically controlled, conclusive testing, Laetrile's effectiveness has been neither proved nor disproved.⁹⁶ Its supporters have marshaled "evidence" in the form of individual patients' success stories.⁹⁷ This kind of anecdotal evidence is dismissed by the medical and regulatory establishment in a fashion that many supporters cannot understand.⁹⁸ The refusal to test and the refusal to accept anecdotal evidence in place of the required clinical tests have inflamed rather than quieted the controversy.⁹⁹

Twenty states have legalized Laetrile within their borders.¹⁰⁰ A Medical Freedom of Choice bill¹⁰¹ has garnered 115 sponsors in the U.S. House of Representatives.¹⁰² The bill would eliminate the requirement of safety.¹⁰³ Reacting to what they perceive as FDA intransigence, and recognizing that it has served merely to prolong rather than answer the question of Laetrile's effectiveness, some prestigious members of the medical establishment have called for clinical testing, which they hope would settle the issue.¹⁰⁴ A few respected physicians have even called for legalizing Laetrile as simply the most expedient way to put the matter to rest.¹⁰⁵ Until recently, the FDA has even resisted the request of another government agency, the National Cancer Institute (NCI), for permission to clinically test Laetrile.¹⁰⁶ This has forced the NCI to engage in a "retrospective" study of the drug in which individual case

93. See Moertel, *A Trial of Laetrile Now*, 298 NEW ENGLAND J. MED. 218, 218-19 (1978).

94. 21 U.S.C. § 355(b) (1976).

95. See, e.g., *Rutherford v. United States*, 399 F. Supp. 1208, 1212-13 (W.D. Okla. 1975), *aff'd on other grounds*, 542 F.2d 1137 (10th Cir. 1976), *rev'd on other grounds*, 442 U.S. 544 (1979), wherein the district court found that the FDA, in refusing to either approve or reject a new drug application for Laetrile, had created a procedural dilemma for plaintiffs, who were unable to appeal the FDA nonaction in the absence of an order.

96. "[O]pponents of Laetrile have no more scientifically acceptable evidence to deny its effectiveness than advocates have to claim such effectiveness. The simple fact is that Laetrile has never been properly studied in the hands of those competent to make such a judgment." Moertel, *A Trial of Laetrile Now*, 298 NEW ENGLAND J. MED. 218, 218 (1978).

97. 42 Fed. Reg. 39,768, 39,797, 39,799 (1977).

98. Moertel, *A Trial of Laetrile Now*, 298 NEW ENGLAND J. MED. 218, 218-19 (1978).

99. *Id.*; Ingelfinger, *Laetrilomania*, 296 NEW ENGLAND J. MED. 1167 (1977); Relman, *Laetrilomania—Again*, 298 NEW ENGLAND J. MED. 215 (1978).

100. N.Y. Times, Jan. 4, 1980, § A, at 11, col. 1.

101. H.R. 54, 96th Cong., 1st Sess. (1979).

102. 36 CONG. Q. 689, 692 (1978).

103. *Id.* The U.S. Senate also amended a section of the Carter Administration's proposed Drug Reform Act (S. 1075), which had sought to give the FDA complete *intrastate* authority. This would have effectively nullified the state laws legalizing Laetrile. *Id.* at 689. The amendments exempt drugs specifically permitted by state statutes from FDA authority. 37 CONG. Q. 2349, 2352 (1979).

104. Moertel, *A Trial of Laetrile Now*, 298 NEW ENGLAND J. MED. 218, 218-19 (1978); Relman, *Laetrilomania*, 298 NEW ENGLAND J. MED. 215, 216 (1978).

105. Crile, *Legalization of Laetrile—A Suggestion*, 295 NEW ENGLAND J. MED. 116 (1976).

106. N.Y. Times, Jan. 4, 1980, § A, at 11, col. 1.

histories were submitted to a scientific panel for evaluation.¹⁰⁷ The results were inconclusive.¹⁰⁸ A dissident group within one of the nation's largest cancer research centers has accused the center of wanting laboratory tests of Laetrile to fail.¹⁰⁹

There is some dissent within the ranks of medical practitioners.¹¹⁰ In one stunning case a physician member of the California Medical Board reportedly admitted, during a hearing by the board to revoke the license of another physician for prescribing Laetrile, that he had prescribed it for his own cancer. The board's counsel, a California assistant attorney general, was quoted as saying that he would have done the same thing.¹¹¹ There is a belief among at least some members of the medical establishment that the government's handling of Laetrile has backfired. For instance, the editor of the prestigious *New England Journal of Medicine*, himself a cancer victim who remains opposed to the use of Laetrile in cancer treatment, has pointed out that "an establishment indictment of a popular remedy is one of the best advertisements for the remedy. Thus when the FDA, the AMA or an esteemed fellow medical editor inveighs against Laetrile, I suspect they are unintentionally increasing the demand."¹¹² A New Jersey court was even more direct: "Unintentionally, those opposed to the use of [L]aetrile may have helped to perpetuate the myth of its remedial value by depriving victims . . . of access to the drug."¹¹³ A physician wrote to his colleagues that "our rhetoric of damnation and indignation is not effective and, indeed, can be counterproductive."¹¹⁴

As will be illustrated below,¹¹⁵ the Laetrile issue has been just as active in state and federal courts. The combination of legislation, litigation, and medical dissension means that "Laetrile is not about to disappear."¹¹⁶ The current situation is that an estimated 75,000 Americans have taken it illegally,¹¹⁷ no one has proven that it does or does not work,¹¹⁸ and it is available only to

107. Newell, *Why the National Cancer Institute Chooses a Case-Record Review of Laetrile*, 298 NEW ENGLAND J. MED. 216 (1978).

108. Ellison, Byar & Newell, *Special Report on Laetrile: The NCI Laetrile Review*, 299 NEW ENGLAND J. MED. 549, 552 (1978).

109. Some employees of Sloan-Kettering Memorial Institute published a critique of the Institute's statement that it had found no evidence that Laetrile is beneficial in cancer treatment. The critique challenged, among other things, the statement's claim that Laetrile had failed in an experimental setting in which conventional anticancer drugs had succeeded; in fact, the critique said, no known anti-cancer drug is effective in the particular setting. 113 SCI. NEWS 4 (1978).

110. 42 Fed. Reg. 39,768, 39,785-86 (1977).

111. San Jose Mercury, April 10, 1974, at 1, cited in Amicus Curiae Brief for Respondent, at 186, *People v. Privitera*, 23 Cal. 3d 697, 591 P.2d 919, 153 Cal. Rptr. 431, cert. denied, 444 U.S. 949 (1979).

112. Ingelfinger, *Laetrilomania*, 296 NEW ENGLAND J. MED. 1167 (1977). *Accord*, Moertel, *A Trial of Laetrile Now*, 298 NEW ENGLAND J. MED. 218, 219 (1978).

113. *Suenram v. Society of the Valley Hosp.*, 155 N.J. Super. 593, 598, 383 A.2d 143, 146 (Law Div. 1977).

114. Moertel, *A Trial of Laetrile Now*, 298 NEW ENGLAND J. MED. 218, 219 (1978).

115. See text accompanying notes 120-212 *infra*.

116. Relman, *Laetrilomania—Again*, 298 NEW ENGLAND J. MED. 215 (1978).

117. *Id.* at 216.

118. Moertel, *A Trial of Laetrile Now*, 298 NEW ENGLAND J. MED. 218, 218-219 (1978).

those who are willing to break the law or travel abroad.¹¹⁹ After examining how a number of courts have dealt with the issue, this Comment will make suggestions for taking the drug out of limbo.

II. LAETRILE CASES AND PRIVACY

A. Rutherford

The leading federal litigation dealing with Laetrile is *Rutherford v. United States*.¹²⁰ The subject of nine orders¹²¹ or opinions and one administrative hearing by the FDA,¹²² *Rutherford* began when a number of terminally ill cancer patients sought to enjoin the government from interfering with their access to Laetrile. The district court found that Laetrile was both safe and effective and ordered the government to permit its use by one,¹²³ and eventually others, of the plaintiffs.¹²⁴ The court reasoned that the denial of freedom of choice for treatment by Laetrile is a deprivation of life, liberty, or property without the due process of law guaranteed by the fifth amendment.¹²⁵ Due process was denied by the FDA's refusal to issue a formal refusal to test Laetrile; without that formal refusal, the plaintiffs could not appeal the FDA inaction on Laetrile to the court of appeals.¹²⁶

The Tenth Circuit allowed the injunction to stand but instructed the district court to remand the case to the FDA for determination whether Laetrile was a "new drug" under the Federal Food, Drug, and Cosmetic Act.¹²⁷ If Laetrile was not a new drug, it could be grandfathered in and would be exempt from the efficacy requirements that apply to new drug applications. Only the drug's safety would then be within the FDA's jurisdiction. Following administrative hearings, the FDA Commissioner issued a decision in July 1977.¹²⁸ He found that there was no uniform definition of Laetrile, that in its various forms Laetrile was a "new drug" under the Act because it was not

119. *Rutherford v. United States*, 438 F. Supp. 1287, 1296, 1300 (W.D. Okla.), *aff'd*, 582 F.2d 1234 (10th Cir. 1977), *rev'd*, 442 U.S. 544 (1979).

120. The history of the *Rutherford* litigation is as follows: *Rutherford v. United States*, 399 F. Supp. 1203 (W.D. Okla. 1975)(remanding to the FDA), *aff'd* 542 F.2d 1137 (10th Cir. 1976)(affirming the district court's remand to the FDA), *on remand*, 424 F. Supp. 105 (W.D. Okla. 1977)(remanding to the FDA), 429 F. Supp. 506 (W.D. Okla. 1977)(again remanding to the FDA and enjoining the FDA from preventing the importation and use of Laetrile by the plaintiffs), 438 F. Supp. 1287 (W.D. Okla. 1977)(again remanding to the FDA and enjoining the FDA from preventing the importation and use of Laetrile by the plaintiffs), *aff'd*, 582 F.2d 1234 (10th Cir. 1978)(affirming the district court's remand to and injunction of the FDA), *rev'd*, 442 U.S. 544 (1979)(reversing and remanding to the court of appeals), *on remand*, 616 F.2d 455 (10th Cir. 1980)(remanding to district court to reverse injunction against FDA), *cert. denied*, 101 S. Ct. 336 (1980).

121. See note 120 *supra*.

122. 42 Fed. Reg. 39,768 (1977).

123. 399 F. Supp. 1208, 1212-14 (W.D. Okla. 1975), *aff'd*, 542 F.2d 1137 (10th Cir. 1976), *rev'd*, 442 U.S. 544 (1979).

124. 429 F. Supp. 506 (W.D. Okla.), *aff'd*, 582 F.2d 1234 (10th Cir. 1977), *rev'd* 442 U.S. 544 (1979).

125. 399 F. Supp. 1208, 1213 (W.D. Okla. 1975), *aff'd*, 542 F.2d 1137 (10th Cir. 1976), *rev'd*, 442 U.S. 544 (1979).

126. *Id.* at 1212-13.

127. 542 F.2d 1137 (10th Cir. 1976), *rev'd*, 442 U.S. 544 (1979).

128. 42 Fed. Reg. 39,768 (1977).

generally recognized as safe and effective for its prescribed use, and that the drug did not qualify for exemption under either of the Act's grandfather clauses.¹²⁹ The district court sustained the Commissioner's findings that Laetrile was a "new drug" because it was not generally recognized as safe and effective.¹³⁰ While sustaining one of the grandfather clause denials,¹³¹ the court refused the other because it depended on a showing that Laetrile was unsafe at the time the clause was adopted—a finding the court held was not substantiated by the evidence presented at the FDA hearings.¹³² The court therefore ruled that Laetrile was entitled to exemption from the rigorous premarketing testing requirements.¹³³ The court also held, for the first time in this case, that "by denying the right to use a nontoxic substance in connection with one's own personal health-care, FDA has offended the constitutional right of privacy."¹³⁴

On appeal, the Tenth Circuit once again affirmed the district court on different grounds.¹³⁵ This time the court of appeals held that the Act's terms of "safe" and "effective" have no reasonable application for terminally ill patients.¹³⁶ The constitutional issue was not addressed.

In a unanimous decision,¹³⁷ the United States Supreme Court reversed the Tenth Circuit. The Court refused to recognize any implied exemption from the purview of the Act for terminally ill patients. It found "no license to depart from the plain language of the Act, for Congress could reasonably have intended to shield terminal patients from ineffectual or unsafe drugs."¹³⁸ The Court accepted the FDA finding that a drug is effective if it fulfills claims of prolonged life, improved physical condition, or reduced pain.¹³⁹ The Court also found that safety of a drug *does* have meaning for terminally ill patients. In a somewhat conclusory statement, the Court said: "For the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit."¹⁴⁰ Justice Marshall's opinion for the Court never explained just how death or injury have meaning for someone who is dying and who has rejected conventional cancer treatment because of its pain or hopelessness. The opinion went on to accept FDA testimony from the Laetrile hearings concerning the

129. *Id.* at 39,806.

130. 438 F. Supp. 1287, 1292-93 (W.D. Okla. 1977), *aff'd*, 582 F.2d 1234 (10th Cir. 1977), *rev'd*, 442 U.S. 544 (1979).

131. *Id.* at 1298.

132. *Id.*

133. *Id.* at 1301.

134. *Id.* In the first *Rutherford* opinion by the district court, the right of privacy was discussed without being invoked. 399 F. Supp. 1208, 1214 (W.D. Okla. 1975), *aff'd*, 542 F.2d 1137 (10th Cir. 1976), *rev'd*, 442 U.S. 544 (1979).

135. 582 F.2d 1234 (10th Cir. 1978), *rev'd*, 442 U.S. 544 (1979).

136. *Id.* at 1236-37.

137. 442 U.S. 544 (1979).

138. *Id.* at 555.

139. *Id.*

140. *Id.* at 555-56.

claimed difficulty of identifying the terminally ill "except in retrospect."¹⁴¹ This evidence was used in support of the contention that a drug such as Laetrile can be unsafe when it diverts a patient from possibly beneficial conventional therapy.¹⁴² This refusal to recognize medicine's ability to identify any patient as terminal until after his death¹⁴³ conveniently resolved the Court's inability to show just how a terminal patient can be hurt by an ineffective or unsafe drug.

The opinion notes that cancer patients for whom regular therapies are ineffective may resort to experimental cancer drugs under the terms of the Act.¹⁴⁴ In so doing, it ignores the practical impossibilities of qualifying drugs that are not developed under the aegis of the large pharmaceutical companies.¹⁴⁵ The FDA requires extensive documentation far beyond the anecdotal claims available for Laetrile.¹⁴⁶ The Court likewise ignored the FDA's long intransigence against any kind of experimental clinical trial of Laetrile—a stubbornness that has even extended to turning down requests from another government agency.¹⁴⁷

The decision was restricted to the Court's reading the Act to encompass terminally ill patients. The Court specifically refused to address the constitutional right of privacy issue and the grandfather clause question—issues that formed the basis for the trial court decision but that were not dealt with by the Tenth Circuit.¹⁴⁸ The case was remanded for further consideration by the court of appeals of those issues.¹⁴⁹ In a brief opinion,¹⁵⁰ the Tenth Circuit reversed the district court's holdings on both the grandfathering of Laetrile and, apparently, on the choice of treatment afforded by the right of privacy. The latter issue was not discussed, the court being content to note "in the context with which we are here concerned that the decision by a patient whether to have a treatment or not is a protected right, but his selection of a particular treatment, . . . is within the area of governmental interest in protecting public health."¹⁵¹ The Supreme Court denied certiorari.¹⁵² The question whether the right of privacy covers a person's right to unconventional medical treatment thus has not been addressed above the district court level in the federal judiciary.

141. *Id.* at 556.

142. *Id.* at 557.

143. *Id.* at 556.

144. *Id.* at 558.

145. One proponent of the Medical Freedom of Choice bill, *see* note 101 *supra*, estimates that the average cost of developing and licensing a new drug is \$12 million. 35 CONG. Q. 1346, 1347 (1977).

146. *See, e.g.*, 21 C.F.R. § 310 (1980) (new drugs); 21 C.F.R. § 312 (1980) (new drugs for investigational use); 21 C.F.R. § 314 (1980) (new drug applications).

147. The National Cancer Institute sought FDA permission to clinically test Laetrile for more than one year. N.Y. Times, Jan. 4, 1980, § A at 11, col. 1.

148. 442 U.S. 544, 559 n.18 (1979).

149. *Id.*

150. 616 F.2d 455 (10th Cir. 1980), *cert. denied*, 101 S. Ct. 336 (1980).

151. 616 F.2d 455, 457 (10th Cir. 1980). The opinion has an air of resignation about it. Although the court mentioned the FDA's "record" with apparent sarcasm, *id.* at 456, it refused to grapple again with a review of the record, presumably because of the Supreme Court's upholding of the FDA's authority and actions. *Id.*

152. 101 S. Ct. 336 (1980).

B. Privitera

The leading state court case applying the right of privacy to the use of Laetrile is *People v. Privitera*,¹⁵³ in which a physician and others who were supplying Laetrile to cancer patients were charged with violating a California statute that makes it a misdemeanor to provide any drug for the treatment of cancer unless it has been approved by either the FDA or a state board.¹⁵⁴ A California court of appeals had reversed the defendants' convictions because, among other things, the statute infringed on the patients' fundamental right of privacy under both the California and United States Constitutions.¹⁵⁵ The appeals court reached much further back than *Griswold*. It found that Americans' right of privacy is older than the Constitution. The court stated, "It is in the nature of man that such right exists."¹⁵⁶ The opinion quoted Judge Cardozo's famous statement that "every human being of adult years and sound mind has a right to determine what shall be done with his own body,"¹⁵⁷ and Justice Brandeis' equally well-known dissent in *Olmstead v. United States*, wherein Brandeis called "the right to be let alone" from government intrusion "the right most valued by civilized man."¹⁵⁸ The opinion then traced the Supreme Court's evolution of the modern right of privacy and concluded that the right to make personal medical decisions—including "foolish" ones—¹⁵⁹ was encompassed by the right of privacy and could be overcome only by the showing of a compelling state interest.¹⁶⁰ It failed to find such an interest in the absolute prohibition of Laetrile to cancer patients.¹⁶¹

The California Supreme Court reversed the court of appeals by holding that the right to drugs of unproven efficacy is not encompassed by the right of privacy under either the United States or California Constitutions.¹⁶² Having failed to find a fundamental privacy right, the court subjected the California cancer drug statute to a rational basis test and, not surprisingly, upheld it.¹⁶³

The court refused to contemplate any enlargement of the federal right of privacy. It purported to show that the United States Supreme Court had fixed the bounds of the right by quoting a passage from *Whalen v. Roe* to the effect that the right involves "matters relating to marriage, procreation, contraception, family relationships and child rearing and education."¹⁶⁴ By omitting the

153. 23 Cal. 3d 697, 591 P.2d 919, 153 Cal. Rptr. 431, cert. denied, 444 U.S. 949 (1979).

154. The defendants argued the patients' right to Laetrile derivatively. *Id.* at 713, 591 P.2d at 928, 153 Cal. Rptr. at 440.

155. 141 Cal. Rptr. 764, 777 (Dist. Ct. App. 1977).

156. *Id.* at 768.

157. *Id.* at 770, quoting *Schloendorff v. Society of New York Hosp.*, 211 N.Y. 125, 129-30, 105 N.E. 92, 93 (1914), overruled on other grounds, 2 N.Y.2d 656, 143 N.E.2d 3, 163 N.Y.S.2d 3 (1957).

158. 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting).

159. 141 Cal. Rptr. 764, 770 (Dist. Ct. App. 1977).

160. *Id.* at 777.

161. *Id.* at 783-84.

162. 23 Cal. 3d 697, 702-09, 591 P.2d 919, 921-26, 153 Cal. Rptr. 431, 433-38, cert. denied, 444 U.S. 949 (1979).

163. *Id.* at 702, 591 P.2d at 921, 153 Cal. Rptr. at 433.

164. *Id.*

*Abortion Cases*¹⁶⁵ from the list, the California court concluded that the right did not involve medical treatment.¹⁶⁶ The California court further ignored United States Supreme Court statements¹⁶⁷ that the boundaries of the right of privacy have not yet been fixed; it treated the matter as a fully developed one, rather than one which is still evolving.

Even though it had decided that no fundamental right of privacy existed in *Privitera*, the California court nevertheless felt constrained to point out that the United States Supreme Court had never found the right to be absolute.¹⁶⁸ Why this should matter, once the right is not found to apply, is unclear. Equally mysterious is the court's grappling¹⁶⁹ with the level of scrutiny used in the *Abortion Cases*.¹⁷⁰ If neither a fundamental right nor a suspect classification is involved, no application of strict scrutiny is called for, regardless of what the United States Supreme Court did in the *Abortion Cases*, or in any other cases involving the right to privacy. The California court was apparently uncomfortable with its conclusory statement¹⁷¹ that a fundamental right of privacy is not at stake where a cancer victim desires unconventional treatment, and sought to dispose of the *Abortion Cases*—the ones most analogous to the issue at hand—in some other manner. This the court attempted to do by asserting that *Roe v. Wade*¹⁷² used a rational basis test “when a danger to health exists.”¹⁷³ In reality, as previously pointed out,¹⁷⁴ the Court continued its high level of scrutiny through all three trimesters, finding the privacy right eventually overcome by the state's compelling interest in the woman's health as the fetus matures and abortion becomes riskier.

The California court then addressed another United States Supreme Court privacy case, *Planned Parenthood of Central Missouri v. Danforth*,¹⁷⁵ and interpreted it to mean that although the abortion decision is within the zone of privacy and deserving of the compelling state interest standard, “the selection of a particular procedure is a medical matter to which privacy status does not attach . . .” and which could be regulated under the rational basis standard.¹⁷⁶ Actually, the Supreme Court rejected the State's preselection of medical procedures in *Planned Parenthood*.¹⁷⁷ Although it failed to refer to the constitutional right of privacy in striking down this prohibition of a

165. *Roe v. Wade*, 410 U.S. 113 (1973); *Doe v. Bolton*, 410 U.S. 179 (1973).

166. 23 Cal. 3d 697, 702, 591 P.2d 919, 921, 153 Cal. Rptr. 431, 433, *cert. denied*, 444 U.S. 949 (1979).

167. “[T]he outer limits of [the privacy interest in making certain kinds of important decisions] have not been marked by the Court . . .” *Carey v. Population Services Int'l*, 431 U.S. 678, 684 (1977).

168. 23 Cal. 3d 697, 703, 591 P.2d 919, 922, 153 Cal. Rptr. 431, 434, *cert. denied*, 444 U.S. 949 (1979).

169. *Id.*

170. *Roe v. Wade*, 410 U.S. 113 (1973); *Doe v. Bolton* 410 U.S. 179 (1973).

171. “[A] fundamental privacy right is not at stake here.” 23 Cal. 3d 697, 702, 591 P.2d 919, 921, 153 Cal. Rptr. 431, 433, *cert. denied*, 444 U.S. 949 (1979).

172. 410 U.S. 113 (1973).

173. 23 Cal. 3d 697, 703, 591 P.2d 919, 922, 153 Cal. Rptr. 431, 434, *cert. denied*, 444 U.S. 949 (1979).

174. See text accompanying notes 14–16, 41–42 *supra*.

175. 428 U.S. 52 (1976).

176. 23 Cal. 3d 697, 703–04, 591 P.2d 919, 922, 153 Cal. Rptr. 431, 434, *cert. denied*, 444 U.S. 949 (1979).

177. 428 U.S. 52, 75–79 (1976).

medical procedure,¹⁷⁸ the fact of omission would appear less conclusive with regard to the level of scrutiny than the fact that a state statute is virtually never struck down under rational basis analysis. This points to a more stringent level of review.

The California court also treated *Whalen v. Roe* as analogous to *Privitera*.¹⁷⁹ In *Whalen v. Roe*,¹⁸⁰ however, the Supreme Court was upholding a state statute regulating the sale of narcotics, whereas in *Privitera* the state was prohibiting outright the distribution of Laetrile. Perhaps mindful of the differences between the two cases, the California court quoted *Whalen v. Roe* out of context: "the State no doubt could prohibit entirely the use of particular [narcotic] drugs."¹⁸¹ The *Privitera* court determined that if the state has the power to ban a drug with a recognized medical use because of its potential for abuse, then "the state clearly has the power to ban a drug not recognized as effective for its intended use."¹⁸² A full reading of the sentence in its original context yields a different interpretation:

Nor can it be said that any individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use needed medication. Although the State no doubt could prohibit entirely the use of particular Schedule II drugs, it has not done so. This case is therefore unlike those in which the Court held that a total prohibition of certain conduct was an *impermissible deprivation of liberty*.¹⁸³

Although the meaning is not crystal clear, it certainly seems like a warning, instead of an invitation, to states that would prohibit rather than regulate. The warning is that the Court considers prohibitions, as opposed to regulations, to be in such different categories that they can be found to be impermissible deprivations. In any event, this speculative passage from *Whalen v. Roe* is dicta.

California Chief Justice Rose Bird, herself a former cancer victim,¹⁸⁴ dissented strongly.¹⁸⁵ Pointing out the lack of a truly effective treatment for cancer,¹⁸⁶ she wrote that in the absence of a clear showing that Laetrile is unsafe, each patient has the right to obtain the drug from a licensed physician who is willing to prescribe it.¹⁸⁷ She reasoned that since cancer is a disease with potentially fatal consequences, the choice of treatment is "one of the more important decisions a person may ever make, touching intimately on his

178. *Id.*

179. 23 Cal. 3d 697, 704, 591 P.2d 919, 922-23, 153 Cal. Rptr. 431, 434-35, *cert. denied*, 444 U.S. 949 (1979).

180. 429 U.S. 589 (1977).

181. 23 Cal. 3d 697, 705, 591 P.2d 919, 923, 153 Cal. Rptr. 431, 435, *cert. denied*, 444 U.S. 949 (1979).

182. *Id.*

183. 429 U.S. 589, 603 (1977) (emphasis added) (footnote omitted).

184. NEWSWEEK, Feb. 28, 1977, at 70.

185. Chief Justice Bird's dissent incorporates most of the court of appeals opinion. 23 Cal. 3d 697, 711-40, 591 P.2d 919, 927-46, 153 Cal. Rptr. 431, 439-58 (Bird, C.J., dissenting), *cert. denied*, 444 U.S. 949 (1979).

186. *Id.* at 711, 591 P.2d at 927, 153 Cal. Rptr. at 439.

187. *Id.*

or her being.”¹⁸⁸ For her, it follows that the right of privacy, under both the Federal and California Constitutions, “prevents the state from interfering with a person’s choice of treatment on the sole grounds that the person has chosen a treatment which the state considers “ineffective.””¹⁸⁹

The Supreme Court declined to resolve the California Supreme Court’s differing views of the federal right of privacy when it refused to grant certiorari.¹⁹⁰

The *Privitera* result stands in contrast to the holdings of most courts that have faced the problem of whether the right to Laetrile falls within the federal right of privacy. One author notes that “a trend towards greater respect for the wishes of the individual—even if they run counter to those of society in preserving life—has become apparent in recent years.”¹⁹¹ As noted above,¹⁹² a number of decisions have affirmed a patient’s right to reject treatment. Given that right, does the patient then have the right to an unproven “remedy” such as Laetrile? Several courts have answered affirmatively.

C. Related Cases

In *Rizzo v. United States*,¹⁹³ a federal district court granted a preliminary injunction against government denial of Laetrile to the plaintiff, who was dying of pancreatic cancer. Although the court refrained from definitive holdings on the application of the privacy doctrine to Laetrile in the context of a preliminary injunction,¹⁹⁴ it noted that the parameters of the privacy right have not been clearly defined and implied that the plaintiff’s situation would qualify for such an application.¹⁹⁵ A New Jersey trial court took an expansive view in *Suenram v. Society of the Valley Hospital*:¹⁹⁶ “The issue here is human liberty and the right of an informed terminal cancer victim to choose which treatment she shall receive from a state-licensed physician.”¹⁹⁷ The court said that the right could not be of a more fundamental nature.¹⁹⁸ A Florida court of appeals held that a patient’s voluntary informed election of a non-harmful treatment not endorsed by the medical profession fell within the zone of privacy guaranteed by the Florida Constitution.¹⁹⁹ The court implied in dicta that the federal right of privacy was also sufficiently broad to encompass such a decision.²⁰⁰ In *United States v. Evers*,²⁰¹ a case similar to the Florida

188. *Id.*

189. *Id.*

190. 444 U.S. 949 (1979).

191. Drake, *What To Do When a Patient Refuses Treatment*, LEGAL ASPECTS MED. PRACTICE, Oct. 1979, at 22.

192. See text accompanying notes 49–66 *supra*.

193. 432 F. Supp. 356 (E.D.N.Y. 1977).

194. *Id.* at 359.

195. *Id.* at 358.

196. 155 N.J. Super. 593, 383 A.2d 143 (Law Div. 1977).

197. *Id.* at 601, 383 A.2d at 147.

198. *Id.* at 602, 383 A.2d at 148.

199. *Rogers v. State Bd. of Medical Examiners*, 371 So. 2d 1037 (Ct. App.), *cert. denied*, 376 So. 2d 76 (Fla. 1979).

200. *Id.* at 1040.

201. 453 F. Supp. 1141 (N.D. Ala. 1978).

case and involving the same alternative, unapproved treatment (chelation therapy drug prescribed for arteriosclerosis), a federal district court spoke of a patient's right, under the privacy doctrine, to receive medical care in accordance with his licensed physician's best judgment.²⁰² A federal district court in California has granted a cancer patient's request for Laetrile.²⁰³

In the well-known Chad Greene case,²⁰⁴ the Massachusetts Supreme Judicial Court, which affirmed denials of the parents' requests for Laetrile treatments for their leukemic child, specifically disclaimed any consideration of the privacy doctrine in reaching its holding.²⁰⁵ The New York Court of Appeals, in reaching an opposite conclusion on a similar petition by parents of a child with Hodgkins' disease,²⁰⁶ focused its opinion on the issue of whether the child was "neglected" under a parental responsibility statute.²⁰⁷ Because the patients in both cases were young minors, efforts to establish their right to an informed freedom of choice would have been complicated and, accordingly, were not addressed by either court.

The contrary results in the two cases can be explained by differing court-perceived efficacies of the disputed treatments. The New York Court of Appeals found some evidence that the so-called nutritional therapy (Laetrile plus various dietary supplements) might be effective, and some evidence that the conventional remedy was failing.²⁰⁸ On the other hand, the Massachusetts Court was faced with "essentially uncontested" evidence that the conventional therapy was controlling Chad Greene's leukemia;²⁰⁹ that the parents' ending of that therapy had been followed by a resumption of the leukemia;²¹⁰ and that the nutritional therapy for Chad Greene was useless and dangerous.²¹¹ Both courts, then, found themselves in the role of assessing the efficacies and side-effects of alternative treatments. Neither one invoked the right of privacy in reaching a decision.

III. RECENT GOVERNMENT ACTIONS ON LAETRILE

In response to the continued pressure for state legalization of Laetrile,²¹² legal proceedings such as *Rutherford*,²¹³ and letters from patients and their physicians, the National Cancer Institute undertook a "retrospective" study

202. *Id.* at 1150.

203. *Carnohan v. United States*, 616 F.2d 1120 (9th Cir. 1980). *Contra*, *Judkins v. United States*, [1978] FOOD DRUG COS. L. REP. (CCH) 38,179 (D. Ore. 1978): "The outer limits of the right to privacy have not yet been determined, but I am satisfied that the right [of a cancer patient to choose Laetrile therapy] does not fall within its perimeter." *Id.* at 38,730.

204. *Custody of a Minor*, ____ Mass. ____, 393 N.E.2d 836 (1979).

205. *Id.* at ____, 393 N.E.2d at 844.

206. *In re Hofbauer*, 47 N.Y.2d 648, 393 N.E. 2d 1009, 419 N.Y.S.2d 936 (1979).

207. *Id.* at 654, 393 N.E.2d at 1011, 419 N.Y.S.2d at 938.

208. *Id.* at 657, 393 N.E.2d at 1014, 419 N.Y.S.2d at 941.

209. ____ Mass. at ____, 393 N.E.2d at 846.

210. *Id.*

211. *Id.*

212. See text accompanying note 100 *supra*.

213. See text accompanying notes 120-49 *supra*.

of Laetrile in 1978.²¹⁴ Unlike a clinical trial, which seeks to compare the responses of two matched groups, one to the drug under trial and the other to a placebo, the NCI retrospectively screened claims of Laetrile cures and submitted them to a panel that looked for objective evidence of the cures.²¹⁵ NCI resisted the clinical trials in part because of what it perceived as the ethical problem of submitting humans to a therapy that had not previously been proven in animal models.²¹⁶

The NCI retrospective was disappointing to all factions. Although hundreds of thousands of physicians were solicited for cases thought to have had objective benefit from Laetrile, only ninety-three were submitted to the agency for evaluation.²¹⁷ The best documented of these were matched with counterpart cases selected from the ranks of the conventionally treated, and submitted to the panel. The panel judged six cases to have evidenced a response. The results were found to be inconclusive.²¹⁸ NCI officials concluded that "this retrospective analysis illustrates the difficulty of drawing inferences about therapeutic efficacy in the absence of properly designed random trials."²¹⁹

It should be noted that the retrospective sought only evidence of the regression of a measurable tumor.²²⁰ Such subjective responses as diminution of pain, regaining of appetite, and feeling of well-being were not scrutinized.²²¹ Thus, the retrospective failed to address one of the primary claims made by Laetrile's proponents. As a test of clinical effectiveness, the retrospective seemed "doomed to failure" from the start, in the words of one medical commentator, who pointed out that, on the one hand, no clinical pharmacologist would accept such evidence for proof of effectiveness, while on the other hand, the American public would not accept it for proof of *ineffectiveness*.²²²

Presumably because of the inconclusive nature of the retrospective trials, the NCI decided to attempt clinical testing. To do this, it had to obtain FDA approval.²²³ After more than a year of seeking such approval,²²⁴ NCI finally obtained a conditional permit requiring it to first perform another test on animals, and then conduct a test on human volunteers to assay the toxicity of Laetrile when ingested in combination with the "metabolic diet" its pro-

214. Newell, *Why the National Cancer Institute Chooses a Case-Record Review of Laetrile*, 298 NEW ENGLAND J. MED. 216 (1978).

215. *Id.* at 217-18.

216. *Id.* at 216.

217. Ellison, Byar & Newell, *Special Report on Laetrile: The NCI Laetrile Review*, 299 NEW ENGLAND J. MED. 549, 552 (1978).

218. *Id.*

219. *Id.*

220. Newell, *Why the National Cancer Institute Chooses a Case-Record Review of Laetrile*, 298 NEW ENGLAND J. MED. 216, 217 (1978).

221. *Id.*

222. Moertel, *A Trial of Laetrile Now*, 298 NEW ENGLAND J. MED. 218, 219 (1978).

223. There is no special exemption for government agencies from the new drug application procedures. 21 U.S.C. § 355 (1977).

224. N.Y. Times, Jan. 4, 1980, § A, at 11, col. 1.

ponents presently favor.²²⁵ If the toxicity is sufficiently low, FDA is expected to permit a full clinical trial. The full trial would be limited, however, to patients for whom conventional therapy has failed or who suffer from cancers with no known method of treatment.²²⁶

Although the FDA permit is a breakthrough for those who wish to resolve the Laetrile issue definitively, it falls short of the kind of trial that is needed for full resolution. For one thing, the insistence on the animal pre-test has been criticized as being postulated on the assumption that animals serve as reliable models for human responses to cancer treatments.²²⁷ For another, restricting the clinical trials to hopeless cases is bound to be seen by many as loading the dice against Laetrile.²²⁸

FDA reluctance to include other than hopeless cases may be due to the agency's fear that doing so would implicitly recognize the right of informed, consenting volunteers to ingest Laetrile instead of conventional drugs. If such a right does not exist—and FDA has argued that it does not—then there is an ethical question of allowing such participation in a clinical trial.²²⁹ Critics of this reluctance have argued that, since Laetrile has never been properly studied in a clinical trial, there is no scientifically acceptable proof of its ineffectiveness.²³⁰ Unlike other purportedly “quack” medicines, it has been legalized in many states.²³¹ Americans overwhelmingly favor legalizing it.²³² It is conservatively estimated that 50,000 persons ingested Laetrile in 1977.²³³ There is also the “lingering doubt” in scientific minds, in the absence of proof to the contrary, that the “overwhelming public acceptance” of the drug may reflect some kind of effectiveness or relief.²³⁴ Considering the number of nonterminal patients who will turn to Laetrile, many of them without proper medical supervision, it seems just as unethical to argue for the present system as for a clinical trial that would involve a representative cross-section of informed, consenting patients.²³⁵ In any case, there are ethical objections to rigid, double-blind clinical trials of *all* proposed cures for a fatal disease: half the patients—those in the control group—will be receiving a useless placebo although they consented to a trial of the drug being tested rather than to the placebo.²³⁶ From the standpoint of the Laetrile opponents, the ethical problem is simply this: *all* of the patients are subjected to what the opponents see as a useless drug.

225. *Id.*

226. *Id.*

227. Moertel, *A Trial of Laetrile Now*, 298 NEW ENGLAND J. MED. 218 (1978).

228. *See, e.g.,* Rutherford v. United States, 438 F. Supp. 1287 (W.D. Okla.), *aff'd*, 582 F.2d 1234 (10th Cir. 1977), *rev'd*, 442 U.S. 544 (1979).

229. Lipsett & Fletcher, *Ethics of Laetrile Clinical Trials*, 297 NEW ENGLAND J. MED. 1183 (1977).

230. Moertel, *A Trial of Laetrile Now*, 298 NEW ENGLAND J. MED. 218 (1978).

231. *Id.*

232. *Id.* at 218–19.

233. *Id.* at 219.

234. *Id.*

235. *Id.*

236. Lipsett & Fletcher, *Ethics of Laetrile Clinical Trials*, 297 NEW ENGLAND J. MED. 1183 (1977).

In sum, the FDA has been reluctant to authorize any testing, however informed and voluntary, of any new drug that has not met its rigid screening standards. To allow informed volunteers to ingest Laetrile, which has not met the pretesting standards, might open the door to recognition of the right of *all* cancer patients to give an informed consent to the purveyors of Laetrile. Ethical problems already exist, however, in current conventional double-blind clinical trials.

IV. THE PRIVACY DOCTRINE SHOULD PROTECT CANCER VICTIMS' ACCESS TO LAETRILE

This Comment will attempt to show that the privacy doctrine encompasses a cancer patient's right to refuse conventional medical treatment, that a patient who has refused conventional treatment is entitled to try unconventional alternative treatments, that the Government's total cancer approach defies rational analysis, and that, in sum, the Government has failed to do a reasonable job of developing state-sanctioned alternatives for most cancer patients and therefore lacks a compelling interest in prohibiting the use of Laetrile.

A. *Right to Refuse Treatment*

The Patient's Bill of Rights endorsed by the American Medical Association recognizes a right to refuse treatment.²³⁷ This right is qualified because it is only as great as the extent permitted by law.²³⁸ With the exception of emergency situations, it seems settled that patients do have the right to refuse treatment, even to the extent of jeopardizing their lives.²³⁹ This right is being increasingly found under the privacy doctrine. A federal court extended the right to a mental patient to reject the pain of conventional cancer treatment in *Rennie v. Klein*.²⁴⁰ Presumably, a sane, knowing patient would also have that right. The privacy doctrine was also invoked in *Runnels v. Rosendale*,²⁴¹ in which a state prison inmate was held to have the right to reject an unwanted operation.

The countervailing government interests include (1) the preservation of life, (2) the protection of the interests of innocent third parties, (3) the prevention of suicide, and (4) the maintenance of the ethical integrity of the medical profession.²⁴² As the right-to-die cases illustrate,²⁴³ the preservation of life interest can be overcome by the patient's right to decide to terminate life when the patient has determined that it is no longer worth living. The govern-

237. See Bandman & Bandman, *There Is Nothing Automatic About Rights*, in *BIOETHICS AND HUMAN RIGHTS* 268, 272 (1978).

238. *Id.*

239. See text accompanying notes 48-66 *supra*.

240. 426 F. Supp. 1131 (D.N.J. 1978).

241. 499 F.2d 733 (9th Cir. 1974).

242. *Superintendent of Belchertown State Sch. v. Saikewicz*, 373 Mass. 728, 370 N.E.2d 417 (1977).

243. See text accompanying notes 48-66 *supra*.

ment interest here must be distinguished from that invoked in public water treatment, vaccination, and other mass-treatment invasions of bodily integrity. In the latter, the government is preserving well people from harm; it is not prolonging anyone's misery; and its "treatments" (purifying water, administering vaccines) have been demonstrably safer than the diseases they prevent.²⁴⁴ In short, the benefits far outweigh the impositions. By contrast, most cancer victims know that their chances of dying are high regardless of what they do,²⁴⁵ and that their state-sanctioned treatments are painful and only moderately effective.²⁴⁶ Rather than preserving life, the state is prolonging misery.

The interests of innocent third parties have been given judicial protection in cases in which a parent has refused treatment, such as a blood transfusion, that is clearly life-saving and that would return the patient to a productive life.²⁴⁷ Similarly, the state's interest in preventing suicide is most likely to be invoked where the treatment is effective, the chance of a full cure is good, and the patient is responsible for others.²⁴⁸ Preservation of the ethical integrity of the medical profession does not demand that all approved cures be forced on the unwilling patient. As the *Quinlan* case demonstrates,²⁴⁹ there is a body of medical opinion that is not averse to withholding treatment from hopeless cases, even when the patient in those cases cannot consent to the withholding,²⁵⁰ and the American Hospital Association's Patient Bill of Rights recognizes the right to decline treatment, subject only to legal, rather than medical, limitations.²⁵¹

As the *Saikewicz* court put it, "The value of life [under the constitutional right of privacy as an expression of self-determination] is lessened not by a decision to refuse treatment, but by the failure to allow a competent human being the right of choice."²⁵²

B. Right to Alternative, Unapproved Treatment

If a patient has the right to refuse treatment, it is arguably but a short step to the proposition that he has the right to unconventional, unsanctioned treatment methods. In the case of Laetrile, if the drug is as ineffective as the FDA

244. See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11, 38-39 (1905) (smallpox vaccination can be compelled, provided it is not dangerous to an individual).

245. Only about one-third of all people who get cancer will be alive five years after treatment. *Rutherford v. United States*, 438 F. Supp. 1287, 1300 (W.D. Okla.), *aff'd*, 582 F.2d 1234 (10th Cir. 1977), *rev'd*, 442 U.S. 544 (1979), quoting AMERICAN CANCER SOCIETY, 1977 CANCER FACTS & FIGURES.

246. See text accompanying notes 73-77 *supra*.

247. See note 66 *supra*.

248. *Id.*

249. 70 N.J. 10, 29, 355 A.2d 647, 657 (1976).

250. *Superintendent of Belchertown State Sch. v. Saikewicz*, 373 Mass. 728, 742, 370 N.E. 2d 417, 426 (1977).

251. Bandman & Bandman, *There is Nothing Automatic About Rights*, in BIOETHICS AND HUMAN RIGHTS 268, 272 (1978).

252. *Superintendent of Belchertown State Sch. v. Saikewicz*, 373 Mass. 728, 742, 370 N.E.2d 417, 426 (1977).

says it is,²⁵³ then its ingestion is the same as no treatment at all. The FDA has argued that the temptation of Laetrile creates the danger of enticing cancer patients to abandon conventional treatments in favor of Laetrile.²⁵⁴ It also claims that Laetrile itself may not be safe under certain conditions.²⁵⁵ To argue that Laetrile should remain illegal because it may tempt cancer victims to abandon conventional treatments is to presuppose a compelling state interest in their continuing the conventional treatments. If this interest is indeed compelling, could it be used to justify the forced consumption of approved cancer cures? The repugnance of the notion provides the answer.

The safety problem is perhaps the most convincing argument against Laetrile's legalization. There is clearly a government interest—even a duty—in protecting its citizens against dangers. This interest can even override an individual's right to bodily integrity, as in mass vaccinations.²⁵⁶ There are, however, distinctions between the Laetrile controversy and such public health interests as vaccinations, clean water and untainted food. First, no one pretends any citizen *wants* disease, dirty water, or tainted food, whereas the Laetrile plaintiffs have made a conscious decision to seek out the drug. As long as the drug stays underground, we cannot know how well educated each user is about its dangers.²⁵⁷ It seems safe to assume, however, that no Laetrile user would want it unless he believed that its benefits outweigh its dangers. Second, the government has failed to provide a safe alternative. A sanctioned treatment that is "a fate worse than death"²⁵⁸ does not compare favorably with the safety of vaccination, clean water, safe food, or fluoridated water. Third, government's traditional public health interests²⁵⁹ have been preventive; their real analogy in the cancer issue would be government measures to *prevent* cancer, as for instance by banning or regulating tobacco consumption.

It is difficult to believe that thousands of Americans deliberately leave proven cancer cures for the gamble of Laetrile. It is more reasonable to suppose that they are either unconvinced of the efficacy of conventional treatments or unwilling to undergo the agony of the side effects. If the former, they are in good company, and even if wrong, are not doing anything but refusing treatment—a right recognized by the courts and the medical profession. If afraid of the pain of conventional treatments, is the answer to force them to undergo the agony? By denying them a choice of treatments, the

253. 42 Fed. Reg. 39,768, 39,806 (1977).

254. *United States v. Rutherford*, 442 U.S. 544, 556-57 (1979).

255. That is, Laetrile may itself be toxic. 42 Fed. Reg. 39,768, 39,786-87 (1977).

256. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

257. *People v. Privitera*, 23 Cal. 3d 697, 738-39, 591 P.2d 919, 945, 153 Cal. Rptr. 431, 457 (Bird, C.J., dissenting), *cert. denied*, 444 U.S. 949 (1979); Moertel, *A Trial of Laetrile Now*, 298 NEW ENGLAND J. MED. 218, 219 (1978).

258. See text accompanying notes 73-77 *supra*.

259. Traditional public health interests include vaccination, clean air, food and water, sewage disposal, and restaurant licensing.

government is effectively doing just that, leading one California justice to conclude that the government is engaging in cruel and inhuman treatment.²⁶⁰

One of the strongest arguments against unleashing a fundamental right of privacy in the drug area is that it might sabotage the whole regulatory structure—that legalizing Laetrile by judicial decree might lead to legalizing bona fide demands for narcotics and other dangerous drugs. The answer is to extend the right to unconventional remedies, under the privacy doctrine, only to those suffering from cancer or other serious disease and who have made an informed rejection of the state-sanctioned remedies. This would not open up new areas of abuse. Almost all narcotics are already legally available, under existing regulatory mechanisms, to cancer patients in pain, in spite of the universally recognized potential dangers of narcotics. Extending patient access to include such unproven treatments as Laetrile does not seem radical in that context.

Interestingly, there is a movement to make marijuana available to cancer victims in order to alleviate the pains of conventional chemotherapy. Marijuana is currently prohibited altogether.²⁶¹ Unlike Laetrile, limited availability of marijuana is being openly sought by cancer researchers in a number of states.²⁶² There is a striking similarity between the arguments of those researchers and the arguments made by Laetrile proponents. Both groups complain of the violent side effects of chemotherapy and the lack of any effective treatment for the side effects.²⁶³ Those states that have enacted permissive laws have typically set up research projects to monitor the results of each experiment and review boards that pass on the qualifications of patients and physicians who wish to participate in the research.²⁶⁴ By arguing for the well-monitored use of marijuana—a substance arguably more controversial than Laetrile—cancer researchers seem to be handling marijuana with more sophistication. Instead of ignoring the pain of treatments, they are doing something; instead of forcing patients underground, they are giving them legal access while at the same time remaining able to observe any benefits that may in fact exist from use of marijuana; and instead of ignoring anecdotal evidence of relief, the proponent physicians are quoting it.²⁶⁵ The FDA may also be taking a more relaxed attitude: it has not appealed the District of Columbia

260. *People v. Privitera*, 23 Cal. 3d 693, 740, 591 P.2d 919, 946, 153 Cal. Rptr. 431, 458 (Newman, J., dissenting), *cert. denied*, 444 U.S. 949 (1979).

261. Marijuana is a Schedule I drug and thus cannot legally be prescribed. 21 U.S.C. §§ 812(b) (1), 812(c) (1976).

262. *American Med. News*, Jan. 26, 1979, at 17–18. See Cohen, *Marijuana: Does It Have a Possible Therapeutic Use?*, 240 J.A.M.A. 1761 (1978).

263. Compare text accompanying notes 75–77 *supra*, with Cohen, *Marijuana: Does It Have a Possible Therapeutic Use?*, 240 J.A.M.A. 1761 (1978).

264. *American Medical News*, Jan. 26, 1979, at 18.

265. The acting director of an Ohio State University cancer clinic, testifying to an Ohio House of Representatives Subcommittee on a proposal to allow limited use of marijuana in medical situations, told of his patients' reactions to marijuana. "The drug, like others, has different effects on different people." One patient whose chemotherapy made her vomit so hard that she broke her spine is now "eating some funny brownies." *Cleveland Plain Dealer*, Jan. 16, 1980, § A, at 11.

Superior Court decision that granted access to marijuana to a glaucoma victim.²⁶⁶

C. *The Right to Know About Medical Alternatives*

Courts have recognized a patient's right to be informed of alternative treatments.²⁶⁷ They have done this when considering whether consent was sufficiently informed in the context of medical malpractice actions.²⁶⁸ The American Medical Association's Judicial Council has also recognized an individual's freedom to elect to receive treatment from outside the ranks of conventional medicine.²⁶⁹ Such attitudes square well with extending the privacy right to include personal medical decisions.

D. *Practical Considerations*

A number of practical reasons can be offered to buttress the foregoing arguments for bringing the choice of unconventional treatment within the privacy doctrine. First, making a substance such as Laetrile available, however restrictively, will serve to demystify it—an argument used by some physicians who oppose Laetrile but who are convinced that it has been handled in a way that increases rather than decreases demand.²⁷⁰ Next, there has been no conclusive showing that the drug is ineffective or dangerous.²⁷¹ Making it available to those who elect to use it would, provided accurate records are kept, serve as the kind of clinical test that the government has refused to conduct for years.²⁷² Laetrile is also more liable to be dangerous as long as it remains underground. There are no standards of purity or strength.²⁷³ Needless to say, there is no government inspection. Since most physicians are reluctant to chance criminal charges, it is likely that most Laetrile users take it without benefit of medical advice or supervision.

Then there is always the chance that it works. Courts which have handled Laetrile cases are remarkably uniform in reserving that question.²⁷⁴ There is, of course, a government-approved method for testing the efficacy of new drugs. The United States method has been criticized as being enormously

266. *United States v. Randall*, 104 DAILY WASH. L. RPTR. 2249 (1976).

267. *Miller v. Kennedy*, 91 Wash. 2d 155, 588 P.2d 734 (1978). See also *Zebarth v. Swedish Hosp.*, 81 Wash. 2d 12, 499 P.2d 1 (1972); *Scaria v. St. Paul Fire & Marine Inst.*, 68 Wis. 2d 1, 227 N.W.2d 647 (1975).

268. *Id.*

269. AMERICAN MEDICAL ASSOCIATION, OPINIONS AND REPORTS OF THE JUDICIAL COUNCIL 18 (1960).

270. Crile, *Legalization of Laetrile—A Suggestion*, 295 NEW ENGLAND J. MED. 116 (1976); Ingelfinger, *Laetrilomania*, 296 NEW ENGLAND J. MED. 1167 (1977); 42 Fed. Reg. 39,768, 39,781 (1977).

271. See text accompanying note 96 *supra*.

272. See text accompanying notes 91-99 *supra*.

273. Davignon, *Contaminated Laetrile: A Health Hazard*, 297 NEW ENGLAND J. MED. 1355 (1977).

274. E.g., "[W]e do not . . . imply any opinion on whether that drug may ultimately prove safe and effective for cancer treatment." *United States v. Rutherford*, 442 U.S. 544, 558 (1979); "[W]e emphasize we are not taking sides on the fiercely contested medical questions regarding Laetrile's safety or efficacy as a cancer drug." *People v. Privitera*, 23 Cal. 3d 697, 708, 591 P.2d 919, 925, 153 Cal. Rptr. 431, 437, *cert. denied*, 444 U.S. 949 (1979).

expensive and time-consuming,²⁷⁵ and efforts are under way to overhaul federal drug testing law in an attempt to alleviate those problems.²⁷⁶ But drug testing will continue to be so expensive that only the major drug companies are able to sponsor it through the preliminary testing in laboratories and animals that is necessary before FDA permission is granted for clinical testing.²⁷⁷ This has led some critics to call for an end to the requirement of controlled clinical trials before drugs can be tested on willing members of the public.²⁷⁸ The Federal Republic of Germany, for one, has decided that controlled clinical trials are no longer required before recognition of new drugs.²⁷⁹

Another practical aspect of persistent importance is the lack of a truly effective cancer cure despite the intensive efforts of the last decade. As long as conventional methods are not producing a cure, why not allow willing, informed patients to, in effect, become guinea pigs for still more substances? Similarly, a highly structured research procedure may not be the most conducive towards the hoped-for breakthroughs. According to one science historian, the first needs of science are independence, originality, dissent, and freedom.²⁸⁰ If the right of a patient to unapproved substances is recognized, the ethical argument against "inflicting" unproven treatments on a consenting, informed patient will diminish considerably. Researchers would be able to bypass the preliminary screening with animals—never proven to be an accurate predictor of human response—²⁸¹ and go directly to consenting human subjects. The onus of the decision would be on the subject, not on the researcher. In any case, when people are dying from a pervasive disease for which there exists no effective cure, it would seem that pragmatic considerations alone would justify less screening for safety—for how much meaning does safety have for a cancer victim desperate for a cure?

Finally, the public's confidence in the medical and government drug regulatory establishment is a matter of great practical importance. As shown above,²⁸² the government's long-time refusal to test Laetrile on volunteers, its pursuit of violators and its insistence on the uselessness of Laetrile in the face of so much testimonial "evidence" have not engendered confidence by the lay public.²⁸³ Without this confidence, ill persons will seek treatment outside the mainstream of orthodox medicine. A physician skeptical of Laetrile has recognized that "concerned citizens [are] now wondering whether the

275. See 36 CONG. Q. 689, 690-92 (1978); 35 CONG. Q. 1346, 1347 (1977).

276. Wehr, *Senate Approves Major Drug Law Revision*, 37 CONG. Q. 2349 (1979).

277. Although the proposed S. 1075 would allow expedited premarket human testing, it would add to existing requirements in other ways, e.g., mandatory package inserts of patient information, and added standards of "identity," "stability" and "bioavailability" for new drugs. *Id.*

278. See 35 CONG. Q. 1346 (1977); Buskhardt & Kienle, *Controlled Clinical Trials and the Importance of Medical Judgment*, in *CONTROVERSIES IN CANCER* 31 (Tagnon & Stagnat, eds., 1979).

279. *Id.*

280. J. BRONOWSKI, *SCIENCE AND HUMAN VALUES* 79-81 (1956).

281. Moertel, *A Trial of Laetrile Now*, 298 NEW ENGLAND J. MED. 218, 219 (1978).

282. See text accompanying notes 79-106 *supra*.

283. Relman, *Laetrilomania—Again*, 298 NEW ENGLAND J. MED. 215 (1978).

medical establishment may be stubbornly overlooking a valuable adjunct in cancer therapy²⁸⁴

E. *Alternatives Less Drastic Than a Total Ban*

The current total ban on Laetrile can also be attacked as ignoring less drastic alternatives. The marijuana testing laws being adopted by a number of states,²⁸⁵ in cooperation with federal agencies, provide a possible model: making a substance available to patients and physicians who are screened by a board of experts, and keeping track of the results as part of a scientific study. The state interest in regulating unproven drugs is still well served, desperate patients have a chance to elect an unapproved drug, and what is effectively a huge, uncontrolled, unscientific mass of underground nonclinical trials is brought into the light of scientific scrutiny. The patients no longer have to leave the mainstream of professional medical care and take their chances with untrained amateurs and drugs of uncertain strength and purity. Instead they would benefit from the supervision of trained physicians, and the drug, being channeled through a government agency capable of inspecting its potency and purity, would be safer.

This does not necessarily open the door to the full-scale resumption of cancer quackery. Removal of laws that totally ban unapproved cancer cures would still leave on the books proscriptions against quackery. Physicians who hold out false hope would remain subject to discipline by state medical boards, and distributors of such drugs as Laetrile would be subject to prosecution if they advertised the unproven drugs as being in fact effective. Finally, as two FDA officials have pointed out, the threat of medical malpractice may have more of a chilling effect on unscrupulous physicians than the existence of criminal sanctions.²⁸⁶

F. *The Total Cancer Regulatory Scheme*

It is possible that, when the Supreme Court finally addresses the application of the privacy doctrine to personal medical decisions, it will decline to include such decisions within the doctrine. This will presumably subject the government's Laetrile ban to the relaxed rational basis test—usually a guarantee of approval. It can be argued, however, that examining the federal government's cancer scheme *in toto* might result in its failing even the rational basis test.

In contrast to the government's total ban on unproven cancer remedies is its permissive attitude toward the distribution of proven cancer causes. The most glaring example is tobacco. It has been sixteen years since the landmark report by the U.S. Surgeon General's Advisory Committee on Smoking and

284. *Id.*

285. American Med. & News, Jan. 26, 1979, at 17-18.

286. Nightingale & Arnold, *How Laetrile Laws Affect MDs*, LEG. ASPECTS MED. PRACTICE Oct. 1978, at 31.

Health,²⁸⁷ which documented the connection between cigarette smoking and lung cancer and heart disease.²⁸⁸ As the District of Columbia Circuit Court of Appeals stated four years later, "The danger cigarette smoking may pose to health is, among others, a danger to life itself."²⁸⁹ One writer says, "Cigarette smoking is, without question, the greatest single public health problem this nation has ever faced."²⁹⁰ Yet cigarettes can still be purchased and consumed legally. They are subject to increasing government regulation, of course; but rather than ban a substance of proven carcinogenic quality, the government has chosen instead to honor the sovereignty of individual choice.²⁹¹ This it does by trying to inform and convince the public not to smoke, or to smoke less.²⁹² Rather than force manufacturers to reformulate their tobaccos and filters, the government has chosen to publicize each brand's content of the suspected carcinogens.²⁹³ In effect, an American who smokes cigarettes is doing so under an informed consent theory. In the name of individual freedom, since the hazard of smoking relates mainly to each individual consumer, each person is warned of the consequences of his decision to smoke, and the choice is his.²⁹⁴

If the smoker is unfortunate enough to contract cancer, however, his individual freedom of choice terminates. He is free to select treatment only from the state-sanctioned alternatives. If he is distressed by their low cure rate and painful side-effects, he is not free to seek out alternatives, even on an informed consent basis. He is thus free to choose the risk of contracting cancer but not free to choose risky alternative treatments. Since cancer is such a dangerous disease, more often fatal than not, the choice to contract it would seem to be the crucial one. The government cancer scheme is even more irrational: not only is tobacco not banned, but its production is encouraged by price supports and export subsidies.²⁹⁵

A government ban on tobacco would almost certainly result in its illegal trade; and that forms a practical reason against such a ban.²⁹⁶ The same reasoning applies to a proscribed drug such as Laetrile, which so many consumers want. Its ban has not diminished demand; it has merely created a huge underground traffic that has made it more expensive and more dangerous. Users are criminalized and shunted out of the mainstream of proper medical care.²⁹⁷

287. U.S. PUBLIC HEALTH SERVICE, SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL (1964).

288. *Id.* at 33.

289. *Banzhaf v. FCC*, 405 F.2d 1082, 1097 (D.C. Cir. 1968). *cert. denied*, 396 U.S. 842 (1969).

290. K. FRIEDMAN, PUBLIC POLICY AND THE SMOKING-HEALTH CONTROVERSY xi (1975).

291. *Id.* at 147.

292. *Id.*

293. *Id.*

294. U.S. PUBLIC HEALTH SERVICE, SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL (1964).

295. K. FRIEDMAN, PUBLIC POLICY AND THE SMOKING-HEALTH CONTROVERSY 157 (1975).

296. *Id.* at 148-49.

297. Relman, *Laetrilomania—Again*, 298 NEW ENGLAND J. MED. 215, 216 (1978).

G. *Laetrile May Work on Faith Only*

The Laetrile controversy has centered on its effectiveness. Proponents claim that it works; detractors insist it does not. There is a third possibility that should be injected into policy considerations on whether the privacy doctrine should include personal medical decisions to undertake unconventional treatments. This is the possibility that Laetrile, while not clinically effective, performs a placebo cure in patients who believe in it.²⁹⁸ The power of faith in healing has had a medical following: "Respectable names in the history of medicine, like Paracelsus, Holmes, and Osler, have suggested that the history of medication is far more the history of the placebo effect than of intrinsically valuable and relevant drugs."²⁹⁹ It is possible that if Laetrile works, it does not do so in a fashion that can be clinically tested. It may work because patients believe that it does. As one physician put it, "Placebos can have profound effects on organic illness, *including incurable malignancies*."³⁰⁰ It is possible, then, that requiring evidence of *clinical* efficacy may deny cancer patients an effective drug—effective in a way that is just as real³⁰¹ as that of an active pharmacological agent.

CONCLUSION

The right of privacy should extend to the intimate decisions involving choice of treatment for a dangerous disease. The extension need not be absolute. Instead, it can be balanced against countervailing government interests. This is in line with previous privacy doctrine decisions by the U.S. Supreme Court.

The Court has avoided addressing the privacy doctrine in the context of Laetrile or other unconventional medical treatments. Individuals are free to contract cancer by ingesting cancer-causing substances. They are not free to choose their treatments. Even in the absence of a definitive ruling on whether such decisions should be protected by a fundamental right of privacy, the cancer regulatory scheme does not withstand even the relaxed rational basis test.

Until definitive clinical tests are authorized, no one will know whether Laetrile works. Tens of thousands of cancer patients will continue using it illegally, subject to added dangers of uninspected, unregulated drugs and treatment. Their faith continues to be heightened by government refusal to give Laetrile its day in the lab. Their faith may be the one ingredient of Laetrile that does work.

Jon Christensen

298. The FDA has hinted at that possibility. See 42 Fed. Reg. 39,768, 39,799 (1977).

299. N. COUSINS, ANATOMY OF AN ILLNESS 45 (1979).

300. *Id.* at 51 (emphasis added), quoting Shapiro, 18 AM. J. PSYCHOTHERAPY 73, 88 (1961).

301. *Id.* at 56-58.